DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0217]

Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses.'' The report contains proposals for legislative, regulatory, and policy changes to the approval process for new animal drugs intended for use in minor species and for minor uses in major species (minor use drugs). This report is the agency's response to the requirement of the Animal Drug Availability Act of 1996 (the ADAA) that the Secretary of Health and Human Services (the Secretary) consider and announce proposals to facilitate approvals for minor use drugs. Implementation of these proposals should result in an increase in the number of approved new animal drugs for use in minor species and for minor uses.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written comments on the report to Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will also accept e-mail comments. They should be labeled as comments, be identified with the docket number found in brackets in the heading of this document, and be addressed to ''jbutlerl@bangate.fda.gov''. The agency will make paper copies of the comments and will place them in the public docket along with the comments submitted in writing.

NAD 1

Submit written requests for single copies of "Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses" to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Enclose one self-addressed adhesive label to assist that office in processing your requests. Copies of this report are also posted on the Center for Veterinary Medicine (CVM) Internet home page at "http://www.fda.gov/cvm".

FOR FURTHER INFORMATION CONTACT:

For questions about section 2(f) of the ADAA: George A. (Bert) Mitchell, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5587, FAX 301–594–1807, e-mail "gmitchel@bangate.fda.gov", or

For further information about the changes proposed in the report to the approval process: Linda Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614, FAX 301–594–2297, e-mail "lwilmot@bangate.fda.gov".

SUPPLEMENTARY INFORMATION:

I. Background.

On October 9, 1996, the President signed the ADAA (Pub. L. 104–250) into law. Enactment of the ADAA reflected Congress' concerns about the lack of availability of approved new animal drugs. Among other things, the legislation recognized particular problems relating to the availability of approved new animal drugs for minor uses in major species and for use in minor species (minor use drugs).

Section 2(f) of the ADAA directs the Secretary to consider legislative and regulatory options for facilitating approval under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) of new animal drugs intended for use in minor species or for minor uses. The ADAA statute further requires the Secretary to announce within 18 months after the date of enactment proposals for legislative or regulatory change to the approval process for new animal

drugs intended for use in minor species or for minor uses. Publication of the notice announcing the availability of ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses, ADAA Minor Use/Minor Species Working Group'' fulfills that statutory obligation.

The authority of the Secretary regarding new animal drug approvals is delegated to the Commissioner of Food and Drugs by 21 CFR 5.10, and that authority is redelegated to the Director and Deputy Director of CVM in 21 CFR 5.83. In order to respond to the ADAA mandate, CVM established a working group of scientific, legal, and policy experts in animal drug approval and minor species issues to explore possible solutions to the problem and to draft a report with proposals. The working group, recognizing that public input was critical to the development of proposals that would most broadly and effectively facilitate approvals, solicited comments from the public through a **Federal Register** document entitled ''Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and Minor Uses'' (62 FR 33781, June 23, 1997).

In addition, on December 19, 1997, CVM posted on its Internet home page a discussion draft entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses.'' The discussion draft, which was identified as a ''working document,'' included discussions of several options for possible change. CVM encouraged the public to comment on the concepts in the working document and to express any related concerns, and asked for comments on a number of specific questions that focused on particular issues.

CVM received 110 comments in response to the two documents. Among those commenting were minor-species producer groups, exotic-animal (e.g., guinea pigs, ornamental fish) breeders, pharmaceutical companies, veterinarians, zoological organizations, the American Veterinary Medical Association, trade associations, pet shop owners, university faculty, and members of other Federal and State regulatory agencies. The comments were extensive, indicating a high level of interest in the draft proposals. All the comments were reviewed and many have been incorporated

into the recommendations. The comments are on file in Docket No. 97N-0217 and may be viewed in the Dockets Management Branch (address above) and on FDA's home page at "http://www.fda.gov".

II. The Report

While the proposals in this report represent FDA's best thinking for facilitating the approval of animal drugs for minor uses and for use in minor species, the report is not intended to represent formal administration position in support of any of the proposals. FDA hopes that the announcement of these proposals will engender further debate on these issues and stimulate the interest of drug sponsors, manufacturers, and individuals who care for and raise animals.

The report describes a range of legislative and regulatory proposals intended to facilitate minor use and minor species drug approvals and to otherwise increase the legal availability of drugs for minor uses and minor species. The proposals are as follows:

1. Creation by Statute of a "Minor Use Animal Drug" Program

2. Enhancement of Existing Programs for Data Development

3. Conditional Drug Approval for Minor Uses With No Human Food Safety Concern

4. An Alternate Process to Provide for Legal Marketing of New Animal Drugs for Minor Species With No Human Food Safety Concern

5. Other Legislative Options

6. Other Changes in Regulation or Policy

FDA has presented a broad array of options in response to the congressional charge to propose changes that would facilitate the approval of new animal drugs for minor species or minor uses. It is the agency's perception that neither the current animal drug approval process nor any other single approval process can adequately address the enormous diversity of minor species for which animal drugs are needed. Each proposal has merit with respect to certain minor species or minor uses.

Many of the proposals require legislative change. Congress recognized the possibility that statutory changes might be needed in its charge at Section 2(f) of the ADAA. On close examination, the existing statutes simply fail to provide adequate options for FDA and sponsors to fully serve the minor species and minor use needs of the literally hundreds of animal species that people care for. To achieve the goal of increasing the availability of safe and effective drugs for minor species and minor uses, FDA concludes that Federal statutes must be amended.

FDA is willing to work with Congress and other concerned parties to further characterize any proposed statutory changes and to assist as requested and as appropriate in their enactment. If the act is amended as a result of these proposals, the agency will focus its efforts on issuing any necessary regulations through notice and comment rulemaking or otherwise implementing the statutory changes as directed. Increasing the availability of drugs for minor species and minor uses increases protection of public and animal health and is a significant issue for FDA.

III. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this report. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number

found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: SEP 16 1998

William B. Schultz
Deputy Commissioner for Policy

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F